Big Data Steering Group update
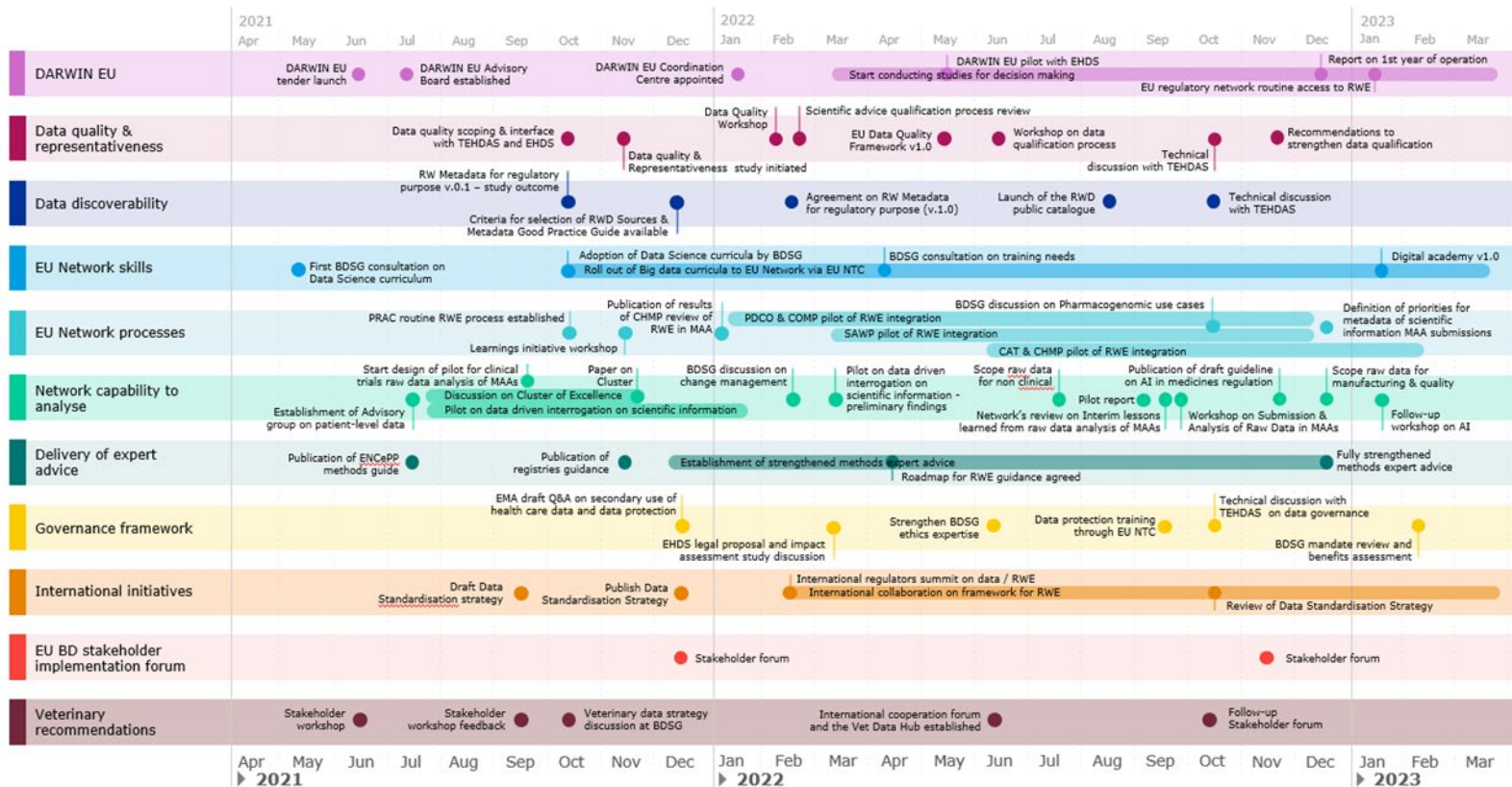
PCWP/HCPWP joint meeting, 1-2 June 2022

Peter Arlett– Co-chair, Big Data Steering Group

Joint HMA-EMA BDSG workplan 2021-2023

On track

DATA QUALITY

EMA/HMA/TEHDAS Data Quality Framework workshop: 7 April 2022

- **Objective: share progress** on building a data quality framework (DQF) for medicines regulation, **solicit feedback**. Thank you for contributions from patients and HCP representatives
- **Next steps:** Workshop report to be published on the EMA website in coming weeks. Feedback to be considered in drafting of the DQF. Written consultation in Q3.

DATA DISCOVERABILITY

Agreement of real-world metadata list for regulatory purposes

- **Metadata list** for real-world data sources for EMRN **prepared** as part of MINERVA study
- **Consultation** of ENCePP, industry and international regulators - **completed**
- Webinar with **EU Network Data Board and TEHDAS** to guide through meta-data list and collect feedback
- Final update and **adoption** of metadata list foreseen by BDSG in Q3

EU NETWORK SKILLS

Launch of the Big Data Curriculum Tender

- Biostatistics, pharmacoepidemiology, data science
- The open tender was **published** on 13 April 2022. Closing date was 31 May 2022
- Framework contract **signature is expected** Q4 **2022**
- Content **development** will therefore **start** from **the end of the year**

STAKEHOLDER ENGAGEMENT

BDSG and industry forum

- **Why:** industry is not represented on the BDSG
- **Objective:** regular (bi-annual) engagement with industry stakeholders (human, vet, medical devices and CROs)
- **Scope**: BDSG workplan activities
- **First meeting:** 30 May 2022 focused on BDSG work planning 2025

DARWIN EU and Raw Data Pilot updates - to follow separately

3rd BDSG workplan to cover 2023-2025

Objective	Review to re-enforce existing Big Data activities and identify gaps for 2023-2025 in line with the EU Network Strategy to 2025

Input	• Learnings Initiative for Optimal Use of Big Data for Regulatory Purpose 30 November 2021
	    • *Contributions from patients and healthcare professionals*
	• Stakeholder feedback from Big Data Forum 7 December 2021
	    • *Contributions from patients and healthcare professionals*
	• Recommendations from existing activities
	• Contributions from EMRN including former HMA–EMA Joint Big Data taskforce members
	    • *Feedback from patients and healthcare professionals via BDSG membership*
	• Input from industry received at BDSG/industry meeting on 30 May 2022

Timelines	• Adoption by BDSG in June 2022 • Publication of the new workplan in July 2022

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Stay up to date on Big Data

- [Big Data webpage](#)

- [Big Data Highlights](#) – Issue 2 published

- [EMA events](#)

- EMA Social media

Concluding remarks

- Steady progress on data transformation delivery as part of the EU Network strategy 2025

- Key - continued involvement of EU patients and healthcare professionals in big data work to realise future benefits

- Recent contributions:

  - Big Data Steering Group workplan 2025 (representation at BDSG)
  - Design of Raw Data Pilot (representation at Advisory Group on Raw Data)
  - DARWIN EU (representation at DARWIN EU Advisory Board)
  - Data Quality Framework workshop on 7 April 2022

Thank you

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